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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/694,243

Applicant(s)

BAO ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-52 and 87-96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7-9,11-17,19,21-26,36-38,40-43,45,47-51,87-91,93,95 and 96 is/are rejected.
- 7) ☒ Claim(s) 2-4, 6, 10, 18, 20, 27-35, 39, 44, 46, 52, 92, and 94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/9/07 wherein claims 1, 7, 8, and 87 were amended; claims 5, and 53-86 were canceled; and claims 95 and 96 were added.

Note: Claims 1-4, 6-52, and 87-96 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments and/or amendment filed 5/9/07 to the rejection of the claims made by the Examiner under 35 USC 102 and/or 103 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

102 Rejection

The 102 rejection is WITHDRAWN. However, it should be noted that all of Applicant's arguments in regards to the cited prior art were not found persuasive. Specifically, Applicant asserted that the magnetic nanoparticles taught by Davis et al do not have a biocompatible coating or any other coating thereon. Davis et al disclose (see abstract, for example) that the magnetic (Fe_3O_4) and semi conducting (CdS) inorganic nanoparticles which were incorporated into macroscopic threads of *Bacillus subtilis* were each (the threads/fibers) coated with a layer of colloidal particles. Thus, the nanoparticles were coated.

103 Rejection

The rejection of claims 1, 7-9, 11-17, 19, 21-26, 36-38, 40-43, 45, 47-51, 87-91 and 93 under 35 USC 103(a) as being unpatentable over Wunderbaldinger et al

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(Bioconjugate Chemistry, 2002, Vol. 13, No. 2, pages 264-268) is MAINTAINED for reasons of record in the office action mailed 2/9/07 and those set forth below.

Applicant asserts that the rejection with respect to independent claim 1 is moot because claim 5 was canceled and the claims were amended to exclude a peptide from the possible targeting probes. In addition, Applicant asserts that claims with respect to independent claim 26, the rejection should be withdrawn because independent claim 26 requires that the claimed compositions comprise two different magnetic nanoparticle probe compositions for use in intracellular molecular imaging.

While Applicant has amended claim 1 to exclude the term 'peptide', independent claim 1 and the appropriate dependent claims are still rejectable under Wunderbaldinger et al because the term 'high affinity ligand' encompasses peptides and other possible ligands. In other words, the phrase encompasses antibodies, antibody fragments, peptides, etc. (see page 32, lines 22-25 of the specification). In addition, page 9, paragraph [025] of the specification discloses various ligands which include proteins, peptides, antibodies, nucleic acid probes, fluorescent dyes, and other molecules. Hence, a skilled practitioner in the art would recognize that while the specific term 'peptide' is omitted from the claims, the term 'high affinity ligand' would encompass peptides.

Applicant's arguments are not found persuasive as they relate to independent claim 26 because the claim does not require that two different compositions be present. The claim requires that two compositions be present, but they do not necessarily have to be different. Wunderbaldinger et al disclose that the synthesis of their magnetic

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nanoparticles involves MION-47, amino-CLIO (crosslinked dextran coated iron oxide), and Tat-CLIO. In particular, it is disclosed that for TAT-CLIO, multiple peptides per nanoparticles are attached. Thus, the skilled artisan would recognize that the claim limitations are met since there are multiple nanoparticles present. As a result, there are multiple compositions present even though the compositions are the same.

Furthermore, Applicant's attention is directed to page 9 (paragraph [0025], lines 7-9) which discloses that different ligands may be conjugated to the composition. Thus, it would have been obvious to a skilled practitioner in the art that the instant invention does not exclude the same ligands from being conjugated in the compositions.

In regards to Applicant's assertion that the cited prior art does not disclose that the compositions are used in intracellular molecular imaging, it should be noted that the composition of the prior art is the same as that being claimed by Applicant. Although the cited prior art does not disclose the particular use, the composition would be capable of having the same use as Applicant's invention since a composition and its properties are inseparable. Thus, Applicant's composition, like the cited prior art's composition, would be 'capable of' performing the same function.

NEW GROUNDS OF REJECTION

112 Second Paragraph Rejections

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 95-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 95 and 96: The format of the claims involving the sequences is confusing since it is unclear the exact ligand sequences being claimed. In the specification, page 16, lines 4-28, the sequences of the ligands is set forth. However, while it appears that Applicant intends to claim only the sequences having the exact sequences disclosed in the specification, the interpretation is not limited to those exact sequences (see explanation below regarding the various interpretations of the claims).

The interpretation of the claim(s) is/are not limited to the specific sequence listed by Applicant. For example, if one has the two sentences below:

(Sentence 1) A composition comprising peptide AM (11-22) of SEQ. ID NO: 1.

(Sentence 2) A composition comprising **the** peptide AM (11-22) of SEQ. ID NO: 1.

The two sentences result in claims of very different scope. The first sentence encompasses peptides that comprise the full length or any portion of SEQ. ID NO: 1. The second sentence claims only peptide sequences that comprise the full length of SEQ. ID NO: 1 with or without additional sequences at either or both ends.

If the claim language is changed to closed (replacing 'comprising' with 'consisting of'), the interpretation of the claim changes.

(Sentence 3) A composition consisting of peptide AM (11-22) of SEQ. ID NO: 1.

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(Sentence 4) A composition consisting of **the** peptide AM (11-22) of SEQ. ID

NO: 1.

Sentence 3 would encompass any peptide sequence wherein SEQ. ID NO: 1 is present. Sentence 4 would be limited to the peptide sequence as specified by SEQ. ID NO: 1 and nothing more or less.

Note: It is respectfully suggested that if Applicant intends the claims to read only on SEQ. ID NO: 1, the phrase 'consisting of the peptide of SEQ. ID NO: 1' should be incorporated into all of the appropriate claims.

CLAIM OBJECTIONS

5. Claims 2-4, 6, 10, 18, 20, 27-35, 39, 44, 46, 52, 92, and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Note: The claims are distinguished over the prior art of record for reasons of record in the office action mailed 2/9/07.

COMMENTS/NOTES

6. Applicant is respectfully requested to make the same changes as suggested for claims 95 and 96 for the dependent claims involving the ligand sequences (see claims 10, 39, and 88).

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7. It should be noted that no prior art has been cited against claims 95 and 96. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the nanoparticle compositions having the limitations as set forth in the claims.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
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August 3, 2007